K121029

SEP 19 2012

SECTION 5:
510(k) SUMMARY

Preparation Date	7th September 2012
Trade Name:	**METS® MODULAR DISTAL FEMUR**
Common Name:	Prosthesis, Knee, Femorotibial, Constrained, Cemented, Metal/Polymer
Classification Name:	Knee joint femorotibial metal/polymer constrained cemented prosthesis (21 CFR 888.3510, Product Code KRO)
Applicant/Sponsor:	Stanmore Implants Worldwide Ltd 210 Centennial Avenue Centennial Park Elstree WD6 3SJ Phone: + 44 (0) 20 8238 6503 Facsimile: +44 (0) 20 8954 0351
Contact Person:	Nancy MacDonald Manager of Regulatory Affairs Health Policy Associates Inc. Email: nmacdonald@healthpolicyassociates.com Tel: (781) 329-2993 Fax: (781) 329-2958
Equivalent to:	JTS Extendible Implant, Stanmore Implants (K092138) Orthopaedic Salvage System (OSS) Biomet (K002757) Global Modular Replacement System (GMRS) Howmedica (Stryker) (K023087) and the Repiphysis Limb Salvage System Wright Medical (K021489)
Device Description:	The single use METS® Modular Distal Femur is a standard modular system that is intended for the replacement of diseased or deficient bone in the distal femur. The stems of the system are intended for cemented use only. The system comprises a range of stems, collars hydroxyapatite (HA) coated or without, (stippled or smooth), a range of shafts, femoral component (including axle, bushes and circlip), bumper and the SMILES knee (available in 3 types of arrangements, and in a rotating or fixed configuration). The materials used in the manufacture of the systems include titanium (Ti), cobalt-chromium-molybdenum (CoCrMo) and ultra high molecular weight polyethylene (UHMWPE).

Intended Use:	The METS® Modular Distal Femur is intended for the replacement of diseased or deficient bone in the distal femur.
Indications for Use:	Limb salvage procedures where radical resection and replacement of the bone is required Painful and disabled joint resulting from avascular necrosis osteoarthritis, rheumatoid arthritis or traumatic arthritis Correction of varus, valgus or post traumatic deformity Correction of revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement Ligament deficiencies Tumor resections Treatment of non-unions, femoral neck and trochanteric fracture of the distal femur with head involvement, unmanageable using other techniques Revision of previously failed total joint arthroplasty Trauma The METS® Modular Distal Femur and its components are for single use only. The METS® Modular Distall Femur and its components are for cemented use only.
Performance Data: (non-clinical and clinical)	<u>Non Clinical Testing</u> The results of the non-clinical performance testing demonstrate that the device is safe and effective and substantially equivalent to the predicate devices. The Performance testing included: knee fatigue and wear test, disassembly force testing for the taper connections, ASTM F1800-07 testing. <u>Clinical Performance Conclusions</u> Clinical evaluation was carried out based upon published papers and post market surveillance.
Substantial Equivalence:	The METS® Modular Distal Femur is equivalent to the JTS Extendible Implant (K092138); Biomet OSS (K002757); the Howmedica (Stryker) GMRS (K023087) and the Repiphysis Limb Salvage System (K021489) predicate devices. The determination of substantial equivalence is based on the similarity of the intended use, indications for use, design/ technological characteristics, materials of composition, method of sterilization, performance data and clinical evaluation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 19 2012

Stanmore Implant Worldwide, Ltd.
% Ms. Nancy MacDonald
Manager, Regulatory Affairs
Health Policy Associates, Inc.
690 Canton Street
Suite 302
Westwood, Massachusetts 02090

Re: K121029
Trade/Device Name: METS Modular Distal Femur
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee joint femorotibial metal/polymer constrained cemented prosthesis
Regulatory Class: II
Product Code: KRO
Dated: September 7, 2012
Received: September 10, 2012

Dear Ms. MacDonald:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4:
INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K121029

Device Name: **METS® MODULAR DISTAL FEMUR.**

Indications for Use:

The METS® Modular Distal Femur is intended for the replacement of diseased or deficient bone in the distal femur. It is indicated for:

Limb salvage procedures where radical resection and replacement of the bone is required
Painful and disabled joint resulting from avascular necrosis osteoarthritis, rheumatoid arthritis or traumatic arthritis
Correction of varus, valgus or post traumatic deformity
Correction of revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement
Ligament deficiencies.
Tumor resections
Revision of previously failed total joint arthroplasty
Trauma

The METS® Modular Distal Femur and its components are for single use only.

The METS® Modular Distal Femur and its components are for cemented use only.

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121029

Prescription Use X AND/ OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)